K130572

Implant Direct
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Sybron Dental Specialties

InterActive/SwishPlus2 Implant System

DEC 2 4 2013

Traditional 510(K) Submission

510(K) Summary (21CFR 807.92(c))

1. **Submitter's Information:**

Company Name:	Implant Direct Sybron Manufacturing LLC
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Registration No.:	3001617766
Contact:	Ines Aravena
Date Prepared:	December 17, 2013

2. **Device Name and Classification:**

Device Trade Name: InterActive/SwishPlus2 Implant System
Classification Names: Implant, Endosseous, Root-Form and Abutment, Implant, Dental, Endosseous
Common Names: Endosseous Dental Implant and Endosseous Dental Implant Abutment
Regulation Number: 872.3630 and 872.3640
Product Codes: DZE and NHA
Regulatory Class: II

3. **Predicate Device(s):**

NobelActive 3.0 (K102436)
NobelActive Internal Connection Implants (K071370)
Spectra-System Dental Implants 2008 (K090234)
Spectra-System Abutments 2008 (K081101)
SwissPlant Dental Implant System (K081396)
Spectra-System (K061319)
Bicon Implants with a 2.5mm Internal Connection (K092035)
Bicon 5.0x5.0mm Dental Implant and 6.0x5.0 Dental Implant (K073368)
Straumann ITI Dental Implant System (K030007)

4. **Device Description:**

The InterActive/SwishPlus2 Implant System consists of InterActive implant, SwishPlus2 implant, abutments, healing components, and screws for use in one or two-stage placement and restorations.

The InterActive implants are two-stage implants that offer four body diameters (3.2, 3.7, 4.3 and 5.0mm) in six lengths (All 6 thru 16mm except for the 3.2 which is 8-16mm). The SwishPlus2 implant body diameters (3.3, 4.1, 4.8, and 5.7mm) in six lengths (All 6 thru 16mm except for the 3.3mm which is 8-16mm).

InterActive Dental Implants

The InterActive dental implant is a tapered screw-type endosseous with an external thread configuration consisting of double-lead threads over the body of the implant and 2mm of quadruple lead mini-threads near the coronal portion of the implant. The implant body features an even taper from the apical along its body and a straight walled coronal aspect. The implants offer two interface diameters (3.0mm and 3.4mm) which are identical to the interface of the predicate devices, NobelActive implants, having a conical leading bevel and an internal hex engaging surface. InterActive implants are prosthetically compatible with InterActive 3.0 and 3.4mm abutments and Nobel Biocare conical connection NobelActive™ NP (Narrow Platform – 3.0mm diameter) and NobelActive™ RP (Regular Platform – 3.4mm diameter) titanium abutments with up to 15° angulations .

InterActive 3.0 and 3.4mm straight titanium abutments, straight temporary abutments, and 15° angled titanium abutments are prosthetically compatible with Nobel Biocare conical connection NobelActive™ NP (Narrow Platform – 3.0mm diameter) and NobelActive™ RP (Regular Platform – 3.4mm diameter) (3.5-5.0mmD, 8.5-18mm Length) implants.

SwishPlus2 Dental Implants

The SwishPlus2 dental implant is a screw-type endosseous with an external thread configuration consisting of single lead threads over the body of the implant and 2mm of micro-grooves near the coronal portion of the implant. The implant body features an even taper at the apical end and a straight wall coronal aspect. The SwishPlus2 (two-stage) implant offer two interface diameters (3.0mm and 3.4mm) which are identical to the interface diameters of the predicate devices, NobelActive implants, having a conical leading bevel and an internal hex engaging surface. SwishPlus2 implants are prosthetically compatible with InterActive 3.0 and 3.4mm abutments and Nobel Biocare conical connection NobelActive™ NP (Narrow Platform – 3.0mm diameter) and NobelActive™ RP (Regular Platform – 3.4mm diameter) titanium abutments with up to 15° angulations .

The InterActive/ SwishPlus2 implants are available with two surface coatings: SBM Blast and HA Coating

5. Intended Use:

InterActive/SwishPlus2 Implant System consists of two-piece implants for one-stage or two-stage surgical procedures. These implants are intended for use in partially and fully edentulous upper and lower jaws in support of single or multiple-unit restorations and terminal or intermediate abutment support for fixed bridgework. Implants can be indicated for immediate loading when good primary stability has been achieved and with appropriate occlusal loading.

Narrow Diameter (3.2, 3.3mm) Implants: Indicated for single-tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. Also indicated for multiple tooth replacements or denture stabilization.

Compatibility: InterActive and SwishPlus2 implants are prosthetically compatible with InterActive 3.0 and 3.4mm abutments and Nobel Biocare conical connection NobelActive™ NP (Narrow Platform – 3.0mm diameter) and NobelActive™ RP (Regular Platform – 3.4mm diameter) abutments. InterActive 3.0 and 3.4mm abutments are prosthetically compatible with Nobel Biocare conical connection NobelActive™ NP (Narrow Platform– 3.0mm diameter) and NobelActive™ RP (Regular Platform – 3.4mm diameter) (3.5-5.0mmD, 8.5-18mmLength) implants.

6. **Device Comparison (Technological Characteristics):**

This submission is comprised of devices whose physical dimensions, material composition, indications for use and methods of manufacture were previously cleared and have the same principles of operation as the cited predicate devices. The following Tables summarize the predicate device comparison analyses with the devices within the InterActive/SwishPlus2 Implant System. The subject device and the predicate devices have the same intended use, the same technological characteristics, implant/abutment interface, similar material and surface treatment.

I. InterActive/SwishPlus2 Dental Implants

Specific Feature	InterActive and SwishPlus2	Predicate Device NobelActive 3.0 (K102436) & NobelActive NP/RP (K071370)	Predicate Device: Legacy+ (K090234)	Predicate Device: SwissPlant (K081396)	Predicate Device: Bicon Implants (K073368 and K092035)	Predicate Device: Straumann (K030007)	Substantial Equivalence
Indications for Use	InterActive/SwishPlus2 Implant System consists of two-piece implants for one-stage or two-stage surgical procedures. These implants are intended for use in partially and fully edentulous upper and lower jaws in support of single or multiple-unit restorations and terminal or intermediate abutment support for fixed bridgework. Implants can be indicated for immediate loading when good primary stability has been achieved and with appropriate occlusal loading. Narrow Diameter (3.2, 3.3mm): Indicated for single-tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. Also indicated for multiple tooth replacements or denture stabilization.	Nobel Biocare's NobelActive implants are endosseous implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Nobel Biocare's NobelActive implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. Nobel Biocare's NobelActive implants may be placed immediately and put into immediate function provided that initial stability requirements detailed in the manual are satisfied. The NobelActive.3.0mm Implant Is Indicated for use In the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to support prosthetic devices, such as artificial teeth, In order to restore chewing function in partially edentulous patients. The NobelActive 3.0 implants may be put into immediate function provided that stability requirements detailed in the manual are satisfied.	Spectra-System Dental Implants 2008 are comprised of dental implant fixtures and prosthetic devices that compose a two-piece implant system. The implants are intended for use in the mandible and maxilla, in support of single unit or multiple unit cement or screw-receiving restorations and for the retention and support of overdentures. The implants are intended for immediate placement and function for the support of singletooth or multiple-tooth restorations, recognizing bone stability and appropriate occusal load requirements.	The SwissPlant Dental Implant system consists of two-piece implants for one or two-stage surgical procedures that are intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including: cement retained, screw retained or overdenture restorations and in terminal or immediate abutment support for fixed bridgework. The SwissPlant dental implants are intended for immediate placement and function on single tooth and/or	The 5.0 x 5.0mm and the 6.0 x 5.0mm implants are designed as a one stage or two stage surgical procedure implant for use in edentulous sites in the mandible or maxilla for support of a complete denture prosthesis, a terminal or intermediate abutment for fixed bridgework, partial dentures, or a single tooth replacement.	The ITI dental implants are intended for immediate placement and function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be rigidly splinted. In the case of edentulous patients 4 or more implants must be used.	√

I. InterActive/SwishPlus2 Dental Implants

Specific Feature	InterActive and SwishPlus2	Predicate Device NobelActive 3.0 (K102436) & NobelActive NP/RP (K071370)	Predicate Device: Legacy+ (K090234)	Predicate Device: SwissPlant (K081396)	Predicate Device: Bicon Implants (K073368 and K092035)	Predicate Device: Straumann (K030007)	Substantial Equivalence
Indications for Use (Cont'd)				multiple tooth applications recognizing initial implant stability and appropriate occlusal loading, to restore normal masticatory function.	The Bicon implant is designed for use in edentulous sites in the mandible or maxilla for support of a complete denture prosthesis, a final or intermediate abutment for fixed bridgework or for partial dentures, or as a single tooth replacement.	may be rigidly splinted. In case of edentulous patients 4 or more implants must be used.	

I. *InterActive/SwishPlus2 Dental Implants*

Specific Feature	InterActive and SwishPlus2	Predicate Device NobelActive 3.0 (K102436) & NobelActive NP/RP (K071370)	Predicate Device: Legacy+ (K090234)	Predicate Device: SwissPlant (K081396)	Predicate Device: Bicon Implants (K073368 and K092035)	Predicate Device: Straumann (K030007)	Substantial Equivalence
Indication	Immediate Load	Immediate Load	Immediate Load	Immediate Load	10-12 weeks	Immediate Load	√
General Design	Threaded groove, root form endosteal implant	Threaded groove, root form endosteal implant	Threaded, root form implant	Threaded, root form implant	Groove type implant	Threaded, root form implant	√
Placement Method	Two stage surgery	Two stage surgery	Two or single stage surgery	Two or single stage surgery	Two or single stage surgery	Two or single stage surgery	√
Material	Titanium 6Al-4V ELI	CP Titanium Grade 4	Titanium 6Al-4V ELI	Titanium 6Al-4V ELI	Titanium 6Al-4V	CP Titanium Grade 4, Roxolid Ti-Zirconia Alloy	√

I. InterActive/SwishPlus2 Dental Implants

Specific Feature	InterActive and SwishPlus2	Predicate Device NobelActive 3.0 (K102436) & NobelActive NP/RP (K071370)	Predicate Device: Legacy+ (K090234)	Predicate Device: SwissPlant (K081396)	Predicate Device: Bicon Implants (K073368 and K092035)	Predicate Device: Straumann (K030007)	Substantial Equivalence
Implant Body Diameters and lengths	InterActive: 3.2mm Dia. X 8-16mm L 3.7mm Dia. X 6-16mm L 4.3mm Dia. X 6-16mm L 5.0mm Dia. X 6-16mm L SwishPlus2: 3.3mm Dia. X 8-16mm L 4.1mm Dia. X 6-16mm L 4.8mm Dia. X 6-16mm L 5.7mm Dia. X 6-16mm L	3.0mm Dia. X 10-15mm L 3.5mm Dia.X 8.5-18mm L 4.3mm Dia.X 8.5-18mm L 5.0mm Dia.X 8.5-18mm L	3.2mm Dia. X 8-16mm L 3.7mm Dia. X 8-16mm L 4.2mm Dia. X 8-16mm L 4.7mm Dia. X 8-16mm L 5.2mm Dia. X 8-16mm L 5.7mm Dia. X 8-16mm L	4.1mm Dia. 6-16mm L 4.8mm Dia. 6-16mm L	Ø 3.0mm x 8mmL Ø 3.5mm x 8-11mmL Ø4.0mm x 5-11mmL Ø 4.5mm x 6-11mmL Ø5.0mm x 5-11mmL Ø6.0mm x 5-8mmL	3.3mm x 8-14mmL (3.5mm Platform) 3.3mm x 8-14mmL (4.8mm Platform) 4.1mm x 6-14mmL (4.8mm Platform) 4.8mm x 6-14mmL (4.8mm Platform) 4.8mm x 6-14mmL (6.5mm Platform)	√
Interface Name	3.0 Platform, 3.4mm Platform	3.0 Platform, NP, RP	3.0mm, 3.5mm,4.5mm, 5.7mm	4.8mm and 6.5mm	2.0, 2.5, 3.0mm Well	4.8 and 6.5mm Platforms	√

I. *InterActive/SwishPlus2 Dental Implants*

Specific Feature	InterActive and SwishPlus2	Predicate Device NobelActive 3.0 (K102436) & NobelActive NP/RP (K071370)	Predicate Device: Legacy+ (K090234)	Predicate Device: SwissPlant (K081396)	Predicate Device: Bicon Implants (K073368 and K092035)	Predicate Device: Straumann (K030007)	Substantial Equivalence
Implant/ Abutment Interface	3.0mm and 3.4mm	2.5mm, 3.0mm, 3.4mm	3.0mm, 3.5mm,4.5mm, 5.7mm	4.8mm and 6.5mm	2.0, 2.5, 3.0mm	4.8 and 6.5mm	√
Engaging Feature	Single 2.3 hex with M1.6 threads, Single 2.7mm hex with M2 threads	Single < 2.3mm hex with M1.6 threads, Single 2.3 hex with M1.6 threads, Single 2.7mm hex with M2 threads	2.0mm and 2.25mm hex with M1.6 threads, 2.5mm hex with 1-72 thread , 3.0mm hex with 1-72 threads	3.10mm Octagon with M2 threads	Single 2.0, 2.5, and 3.0mm Internal Taper Lock with friction fit for antirotation and retention	Single 3.1mm Internal Octagon with M2 Threads for retention	√

I. InterActive/SwishPlus2 Dental Implants

Specific Feature	InterActive and SwishPlus2	Predicate Device NobelActive 3.0 (K102436) & NobelActive NP/RP (K071370)	Predicate Device: Legacy+ (K090234)	Predicate Device: SwissPlant (K081396)	Predicate Device: Bicon Implants (K073368 and K092035)	Predicate Device: Straumann (K030007)	Substantial Equivalence
Surface Treatment	SBM : Soluable Blasted Media surface with roughness between 1.5 µm and 2.3 µm or HA: Soluable Blasted Media surface with roughness between 1.5 µm and 2.3 µm at 3.5mm coronal section and HA coated surface with thickness of 5-15 microns on the rest of the body length	TiUnite: Nobel Biocare's proprietary titanium oxide dental implant surface	SBM : Soluable Blasted Media surface with roughness between 1.5 µm and 2.3 µm or HA : Soluable Blasted Media surface with roughness between 1.5 µm and 2.3 µm at 3mm coronal section and HA coated surface with thickness of 35-60 microns on the rest of the body length	SBM : Dual Soluable Blasted Media surface with roughness between 0.3 µm and 0.9 µm in the collar section and 1.5 µm and 2.3 µm in the body section	Integra-Ti and Integra-CP	SLA and SLActive	√

I. InterActive/SwishPlus2 Dental Implants

Specific Feature	InterActive and SwishPlus2	Predicate Device NobelActive 3.0 (K102436) & NobelActive NP/RP (K071370)	Predicate Device: Legacy+ (K090234)	Predicate Device: SwissPlant (K081396)	Predicate Device: Bicon Implants (K073368 and K092035)	Predicate Device: Straumann (K030007)	Substantial Equivalence
Compatibility with Abutments	Prosthetically compatible with InterActive 3.0 and 3.4mm abutments and Nobel Biocare conical connection NobelActive™ NP (Narrow Platform – 3.0mm diameter) and NobelActive™ RP (Regular Platform – 3.4mm diameter) abutments	Nobel Biocare conical connection NobelActive™ NP (Narrow Platform – 3.0mm diameter) and NobelActive™ RP (Regular Platform – 3.4mm diameter) abutments	N/A	N/A	N/A	N/A	√

II. Cement Retained Angled Contoured Abutments			
Technological Characteristics	**InterActive Cement Retained Angled Abutments**	**Predicate Devices: 36668, 36673 (K071370)**	**Substantial Equivalence**
Intended Use	To be used as a post to support the cemented prostheses for single or multiple restorations	To be used as a post to support the cemented prostheses for single or multiple restorations	√
General Design	2.3 or 2.7 mm hex engaging feature with a 15 degree post and a prosthetic margin	2.3 or 2.7mm hex engaging feature with a 15 degree post and a prosthetic margin	√
Material	Titanium alloy	Titanium alloy	√
Implant/abut Platform	3.0, 3.4mm	3.0, 3.4mm	√

III. Cement Retained Straight and Straight Contour Abutments			
Technological Characteristics	**InterActive Cement Retained Straight Abutments**	**Predicate Devices: P/N 36665, 36669 (K071370)**	**Substantial Equivalence**
Intended Use	To be used as a post to support the cemented prostheses for single or multiple restorations	To be used as a post to support the cemented prostheses for single or multiple restorations	√
General Design	2.3 or 2.7mm hex engaging feature with a straight post and a prosthetic margin	2.3 or 2.7mm hex engaging feature with a straight post and a prosthetic margin	√
Material	Titanium alloy	Titanium alloy	√
Implant/abut Interface	3.0 – 3.4mm	3.0 – 3.4mm	√

IV. **Screw-Receiving Overdenture Abutments**			
Technological Characteristics	**InterActive Screw-Receiving Overdenture Abutments**	**Predicate Devices: P/N 36611, 36616 (K071370)**	**Substantial Equivalence**
Intended Use	To be used as a transmucosal extension for the fabrication of screw-retained multiple-unit prosthesis	To be used as a transmucosal extension for the fabrication of screw-retained multiple-unit prosthesis	√
General Design	Screw-in abutment that does not engage the internal hex connection of the implant	Screw-in abutment that does not engage the internal hex connection of the implant	√
Material	Titanium alloy	Titanium alloy	√
Implant/abut Interface	3.0, 3.4mm	3.0, 3.4mm	√
V. **Screw Receiving Overdenture Angled Abutments with Optional Ball Tops**			
Technological Characteristics	InterActive Screw-Receiving Overdenture Angled Abutments with optional Ball Tops	Predicate Devices: P/N 6035-65-30 (K081101)	**Substantial Equivalence**
Intended Use	To be used as a transmucosal extension for the fabrication of screw-retained multiple-unit prosthesis	To be used as a transmucosal extension for the fabrication of screw-retained multiple-unit prosthesis	√
General Design	Implant engaging feature with a 30 degree angled base and a threaded top to received the overdenture prosthetics	Implant engaging feature with 30 degree angled base and a threaded top to received the overdenture prosthetics	√
Material	Titanium alloy	Titanium alloy	√
Implant/abut Interface	3.0, 3.4mm	3.5 – 6.0 mm	√
VI. **Gold Engaging Abutments**			
Technological Characteristics	**InterActive Gold Engaging Abutments**	**Predicate Devices: P/N 36728, 36729 (K071370)**	**Substantial Equivalence**
Intended Use	To be used as a castable	To be used as a castable	

	abutment for single or multiple restorations	abutment for single or multiple restorations	√
General Design	Gold cylinder with hex engaging feature and castable plastic sheath	Gold cylinder with hex engaging feature and castable plastic sheath	√
Material	Gold Alloy 6019	Gold Alloy 6019	√
Implant/abut Interface	3.0, 3.4mm	3.0, 3.4mm	√

VII. Gold Non-Engaging Abutments

Technological Characteristics	**InterActive Gold None-Engaging Abutments**	**Predicate Devices: P/N 36726, 36727 (K071370)**	**Substantial Equivalence**
Intended Use	To be used as a castable abutment for single or multiple restorations	To be used as a castable abutment for single or multiple restorations	√
General Design	Gold cylinder with castable plastic sheath	Gold cylinder with castable plastic sheath	√
Material	Gold Alloy 6019	Gold Alloy 6019	√
Implant/abut Interface	3.0, 3.4mm	3.4 – 3.9/ 3.4 – 6mm	√

VIII. Ball Abutments

Technological Characteristics	**InterActive Ball Abutments**	**Predicate Device: 8530-71 (K090234)**	**Substantial Equivalence**
Intended Use	To be used for cap attachment overdenture applications	To be used for cap attachment overdenture applications	√
General Design	Ball receiving cap attachment systems with thread engaging feature	Ball receiving cap attachment systems with thread engaging feature	√
Material	Titanium alloy	Titanium alloy	√
Implant/abut Interface	3.0, 3.4mm	3.0mm	√

IX. Straight Full Contour Abutments

Technological Characteristics	**InterActive Straight Full Contour Abutments**	**Predicate Devices: P/N 8530-30L (K090234)**	**Substantial Equivalence**
Intended Use	To be used as a post to support the cemented prostheses for single or multiple restorations	To be used as a post to support the cemented prostheses for single or multiple restorations	√
General Design	2.3, 2.7mm hex engaging feature with a straight post	2.0mm hex engaging feature with a straight post	√
Material	Titanium alloy	Titanium alloy	√
Implant/abut Interface	3.0, 3.4mm	3.0mm	√

X. Temporary Plastic Engaging Abutments			
Technological Characteristics	**InterActive Temporary Plastic Abutments**	**Predicate Devices: P/N 8530-47 (K090234)**	**Substantial Equivalence**
Intended Use	To be used as a temporary post to support the provisional prostheses for single or multiple restorations	To be used as a temporary post to support the cemented prostheses for single or multiple restorations	√
General Design	2.3 – 2.7mm hex engaging feature with a straight post	2.0mm hex engaging feature with a straight post	√
Material	PEEK	PEEK	√
Implant/abut Interface	3.0, 3.4mm	3.0mm	√

XI. Temporary Titanium Non-Engaging Abutments			
Technological Characteristics	**InterActive Temporary Titanium Abutments**	**Predicate Devices: P/N 36661 and 36662 (K071370)**	**Substantial Equivalence**
Intended Use	To be used as a temporary post to support the provisional prostheses for multiple restorations	To be used as a temporary post to support the provisional prostheses for multiple restorations	√
General Design	3.0 – 3.4 non-engaging interface with a straight post	3.0 – 3.4 non-engaging interface with a straight post	√
Material	Titanium alloy	Titanium alloy	√
Implant/abut Interface	3.0, 3.4mm	3.0, 3.4mm	√

The InterActive/SwishPlus2 implants were shown to be substantially equivalent to the predicate devices.

7. **Non-clinical Performance Testing:**

The devices in this submission have mechanical safety (strength) equivalent to the predicate devices. Laboratory testing was conducted for the worst-case devices following FDA "Class II Special Control Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments" and ISO 14801 in static compression bending and fatigue, as well as implant driving torque and abutment/screw torque to failure tests. The components have shown to exhibit equivalent mechanical strength as the predicate devices and the implant/abutment combinations were able to withstand loads that were higher than the functional masticatory loads. Sterilization Validation was carried out in accordance with ISO 17665 -1&2 meeting the requirements and complying with the standards.

8. Clinical Performance Testing

No clinical testing was performed. The clinical evaluation was used to support this decision.

9. Conclusion:

The information submitted in this 510(k) for the InterActive/SwishPlus2 Implant System have shown that the devices are substantial equivalent to the device systems identified as predicates and it is considered that the new devices are compatible and perform as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 24, 2013

Implant Direct Sybron Manufacturing LLC
Ms. Ines Aravena
Senior Director of Product Design and Regulatory Affairs
27030 Malibu Hills Road
CALABASAS HILLS, CA 91301

Re: K130572
Trade/Device Name: InterActive / SwishPlus 2 Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: November 25, 2013
Received: November 26, 2013

Dear Ms. Aravena:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

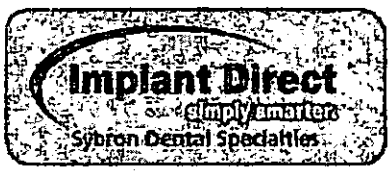
You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer -S FDA for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



Traditional 510(K) Submission

Indications for Use

510(k) Number (if known): K130572

Device Name: InterActive/SwishPlus2 Implant System

Indications for Use:

InterActive/SwishPlus2 Implant System consists of two-piece implants for one-stage or two-stage surgical procedures. These implants are intended for use in partially and fully edentulous upper and lower jaws in support of single or multiple-unit restorations and terminal or intermediate abutment support for fixed bridgework. Implants can be indicated for immediate loading when good primary stability has been achieved and with appropriate occlusal loading.

Narrow Diameter (3.2, 3.3mm) Implants: Indicated for single-tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. Also indicated for multiple tooth replacements or denture stabilization.

Compatibility: InterActive and SwishPlus2 implants are prosthetically compatible with InterActive 3.0 and 3.4mm abutments and Nobel Biocare conical connection NobelActive™ NP (Narrow Platform – 3.0mm diameter) and NobelActive™ RP (Regular Platform – 3.4mm diameter) abutments. InterActive 3.0 and 3.4mm abutments are prosthetically compatible with Nobel Biocare conical connection NobelActive™ NP (Narrow Platform– 3.0mm diameter) and NobelActive™ RP (Regular Platform – 3.4mm diameter) (3.5-5.0mmD, 8.5-18mmLength) implants.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
2013.12.23
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